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October 13, 2011



Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e)
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with Section 8(e): Results of a Repeated Dose 28-Day Oral Toxicity Study in Male Wistar Rats with (Tinuvin 144); Propanedioic acid, [[3,5-bis(1,1-dimethylethyl)-4- hydroxyphenyl]methyl]butyl-, bis(1,2,2,6,6-pentamethyl-4- piperidiny) ester (CAS No. 63843-89-0)

Dear Section 8(e) Coordinator:

BASF Corporation is submitting results of a Repeated Dose 28-Day Oral Toxicity Study in Male Wistar Rats [CrI:WI(HAN)] with (Tinuvin 144); Propanedioic acid, [[3,5-bis(1,1-dimethylethyl)-4- hydroxyphenyl]methyl]butyl-, bis(1,2,2,6,6-pentamethyl-4- piperidiny) ester (CAS No. 63843-89-0), conducted by BASF SE, Ludwigshafen, Germany. The substance is a light stabilizer and antioxidant in adhesives and sealants.

The aim of the study was to determine the toxicological profile of the test substance including the target organs and the "no observed adverse effect level" (NOAEL) of the test substance after 28-day oral administration in the male rat.

The test substance was administered by gavage to groups of 5 male Wistar rats for up to 28 days. The concentration levels were 0, 5, 25, 50 and 75 mg/kg body weight/day. Food and water consumption as well as body weights were determined once a week.

On study day 14, the high-dose group was sacrificed moribund because of severe clinical findings. On study day 22, the high mid-dose group (50 mg/kg bw/d) was sacrificed moribund because of severe clinical findings. At necropsy, these animals were only assessed by gross pathology. On study day 28, all surviving animals were sacrificed and examined by gross pathology. In addition, examination of liver, spleen and thymus weights as well as hematology parameters were performed.



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The following is a summary of the most relevant results:

75 mg/kg body weight/day (treatment of 14 days):

- All male animals were sacrificed moribund on study day 14
- Body weight loss in all animals
- Reduced food consumption on study days 7 and 14
- Reduced water consumption on study day 14
- Piloerection in all animals starting on study day 8
- Poor general condition in all animals starting on study day 9
- Thickening of duodenum wall in all animals
- Enlarged liver in all animals
- Enlarged liver lymph node in 1 animal
- Reduced prostate size in all animals
- Reduced size of seminal vesicle in all animals
- Reduced thymus size in 3 animals

50 mg/kg body weight/day (treatment of 22 days):

- All male animals were sacrificed moribund on study day 22
- Body weight loss in all animals
- Reduced food consumption on study day 21
- Piloerection in 3 animals starting on study day 16
- Poor general condition in all animals starting on study day 21
- Hunched posture in 3 animals
- Intermittent respiration in 2 animals
- High-stepping gait in 1 animal
- Thickening of duodenum wall in all animals
- Enlarged liver in all animals
- Enlarged liver lymph node in 2 animal
- Enlarged spleen in 4 animals
- Reduced prostate size in all animals
- Reduced size of seminal vesicle in all animals
- Reduced thymus size in 1 animal



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25 mg/kg body weight/day (treatment of 28 days):

- Reduced body weight and body weight gain when compared to control animals
- Reduced food consumption on study day 28
- Thickening of jejunum wall in all animals
- Enlarged liver in 1 animal
- Enlarged mesenteric lymph nodes in all animals
- Enlarged spleen in 2 animals
- White foci in spleen of 3 animals
- Decreased terminal body weights
- Decreased red blood cell (RBC) counts, haemoglobin and hematocrit values
- Increased relative liver weights
- Increased absolute and relative spleen weights
- Increased platelet counts
- Increased total white blood cell counts
- Increased absolute and relative neutrophils counts
- Increased absolute and relative monocytes counts
- Increased absolute and relative large unstained cells (LUC) counts
- Increased absolute eosinophils and basophils counts
- Decreased relative lymphocytes counts

5 mg/kg body weight/day (treatment of 28 days):

- Increased total white blood cell counts
- Increased absolute and relative neutrophils counts
- Increased absolute and relative monocytes counts
- Increased absolute eosinophils counts
- Decreased relative lymphocytes counts

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

If you have any questions, please contact the undersigned at (973) 245-6693.

Sincerely,

Janet Cerra

Janet Cerra

Product Regulatory Center of Expertise, North America

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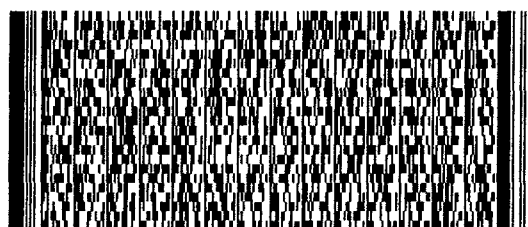
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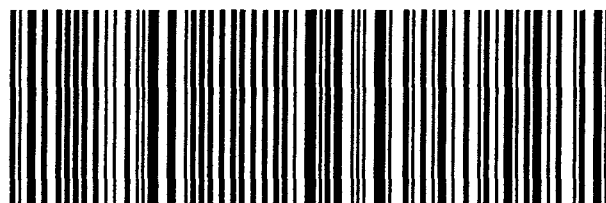
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